IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
ERIE DIVISION

UNITED STATES OF AMERICA, *ex rel.*	:	
DILBAGH SINGH, M.D., PAUL KIRSCH, M.D.,	:	
V. RAO NADELLA, M.D., and	:	**Civil Action No. 04-186E**
MARTIN JACOBS, M.D.,	:	
	:	
Relators,	:	
	:	
v.	:	
	:	
BRADFORD REGIONAL MEDICAL CENTER,	:	
V & S MEDICAL ASSOCIATES, LLC,	:	
PETER VACCARO, M.D.,	:	
KAMRAN SALEH, M.D.,	:	
and DOES I through XX,	:	
	:	
Defendants.	:	

DEFENDANTS' MEMORANDUM
IN SUPPORT OF JOINT MOTION TO DISMISS

Defendants Bradford Regional Medical Center, V & S Medical Associates, LLC, Peter Vaccaro, M.D. and Kamran Saleh, M.D. (collectively, Defendants"), by and through their undersigned counsel, file the following Memorandum of Law in support of their Joint Motion to Dismiss Relators' Complaint in the above-captioned action.

I. INTRODUCTION

This action was brought by Dilbagh Singh, M.D., Paul Kirsch, M.D., V. Rao Nadella, M.D., and Martin Jacobs, M.D. ("Relators") on behalf of the United States Government under the *qui tam* provisions of the False Claims Act. 31 U.S.C. § 3729 *et seq.* However, as set forth

in further detail below, the Complaint (i) fails to state averments of fraud or the circumstances constituting fraud or the circumstances constituting fraud with sufficient particularity as required by Federal Rule of Civil Procedure 9(b), (ii) bases claims on certifications that allegedly were made in a Medicare cost report that could not have been filed at the time the Complaint was filed, and (iii) fails to assert the required elements under 42 U.S.C. § 1395nn (i.e., the "Stark Law"), as the Relators fail to allege the direct or indirect financial relationship that must exist in order to assert a claim under the Stark Law. Therefore, the Complaint fails to state a claim for which relief can be granted and should be dismissed as to all Defendants with prejudice.

II. FACTUAL ALLEGATIONS

The Complaint alleges that Bradford Regional Medical Center ("BRMC"), a not-for-profit hospital, entered into an Equipment Sublease (the "lease") with V&S Medical Associates, LLC ("V&S"), an entity owned by two physicians on BRMC's medical staff – Peter Vaccaro and Kamran Saleh ("Drs. Vaccaro and Saleh"). Complaint ¶¶ 12-15 and 79. A copy of the lease is attached to the Complaint. Relators contend that the lease violated the Medicare anti-kickback statute, 42 U.S.C. § 1320a-7b(b), and the prohibition on certain physician "self-referrals" contained in the so-called "Stark Law." 42 U.S.C. § 1395nn. Complaint ¶ 2. Based on their contention that the lease violated the anti-kickback statute and the Stark Law, the Relators further contend that Defendants: (i) presented "false or fraudulent" claims for reimbursement from the Medicare, Medicaid and CHAMPUS for patients "unlawfully referred" to BRMC by "physicians"; (ii) made false certifications to the Government in connection with cost reports filed with those programs; and otherwise conspired with each other to submit the allegedly false

claims. Complaint ¶¶ 2-6. The United States Attorney's office has informed the Court that the Government has declined to intervene in the action.

All of the counts directed against Defendants are brought under the False Claims Act, which, in relevant part, imposes civil money penalties upon the following:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government … a false or fraudulent claim for payment or approval; (2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government; … or (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the government.

31 U.S.C. § 3729(a).

The Complaint is so vague and its allegations so conclusory, that it is difficult to tell exactly what specific actions any of the Defendants are charged with. The Complaint is long on generalities (not always accurately stated) about federal healthcare reimbursement rules, but short on specifics, such as exactly what false claims were supposedly submitted to the Government, by whom, and when. This is not surprising, since the key allegations about claims being made for patients referred to BRMC by Drs. Saleh and Vaccaro were only made "upon information and belief." Complaint ¶¶ 91-92. At one point, the Complaint even confuses

BRMC with another hospital named in a contemporaneous *qui tam* action filed by the same law firm representing the Relators.[1]

Beyond the lack of direct knowledge and failure to specifically plead the elements of fraud as required by Rule 9(b), the Complaint fails to state a claim for which relief can be granted on additional grounds. The lease attached to the Complaint on its face cannot violate the Stark Law, and the cost reports for the period when the lease was effective were not even filed when the Complaint was filed. The Complaint should therefore be dismissed under Rule 12(b)(6) as well.

III. ARGUMENT

A. Legal Standard

"In a Rule 12(b)(6) motion, the court evaluates the merits of the claims by accepting all allegations in the complaint as true, viewing them in the light most favorable to the plaintiffs, and determining whether they state a claim as a matter of law." Hedges v. U.S., 404 F.3d 744 (3d Cir. 2005) quoting Gould Elec. Inc. v. U.S., 220 F.3d 169, 178 (3d Cir. 2000). A complaint shall be dismissed if "it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." H.J. Inc. v. Northwestern Bell Tel. Co., 492 U.S. 229, 249-50 (1989) (quoting Hishon v. King & Spaulding, 467 U.S. 69, 73 (1984); Conley v. Gibson, 355 U.S. 41, 45-46 (1957). Motions to dismiss are properly granted when a plaintiff fails to conform with the requirements of Rule 9(b) which require that fraud be pleaded with

---

[1] Paragraph 32 refers to "Tyrone Hospital." See U.S. *ex rel.* Bartlett v. Tyrone Hospital, Civil Action No. 04-57 (W.D.Pa. Johnstown Division)

particularity. California Public Employees Retirement System v. Chubb Corporation, 394 F.3d. 196 (3d Cir. 2004). The Complaint should be dismissed under both of these rules.

B. The Complaint Fails to Satisfy the Specificity Requirements of Rule 9(b)

1. The Complaint Fails to Plead Fraud with Particularity

Federal Rule of Civil Procedure 9(b) requires that, "(i)n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Rule 9(b) has been expressly held to apply to *qui tam* cases, and plaintiffs are required to plead fraud with particularity, specifying the time, place and substance of the defendants' alleged conduct. U.S. *ex rel.* Lacorte v. Smithkline Beecham Clinical Laboratories, Inc., 149 F.3d 227, 234 (3d Cir. 1998). Evidence of a false claim is "the *sine qua non* of a False Claims Act violation." U.S. *ex rel*. Clausen v. Laboratory Corporation of America, 290 F.3d 1301, 1311 (11th Cir. 2002), cert. denied 537 U.S. 1105 (2003). Rule 9(b) requires "that a relator must provide details that identify particular false claims for payment that were submitted to the government." U.S. *ex rel.* Karvelas v. Melrose-Wakefield Hospital, 360 F.3d 220, 232 (1st Cir. 2004). Examples of the particulars that would meet this requirement include:

> ...the dates of claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on these practices.

Id. at 233.

While all of this specific information need not be alleged in every case, "some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b)."

Clausen, *supra* at 1312, f.n. 21. Allegations of fraud made "on information and belief," are also subject to Rule 9(b)'s specificity requirements and must set forth the facts on which the belief is founded. Karvelas, 360 F.3d at 226. Relators may not "hypothesize" false claims based on alleged illegal activities, but must come with "claim in hand." U.S. *ex rel.* Schmidt v. Zimmer, Inc., 2005 WL 1806502 (E.D.Pa. July 29, 2005). In Schmidt, the District Court held that a relator in a *qui tam* action cannot simply allege an illegal scheme, and then hypothesize that false claims must have been submitted, without presenting to the court even one specific actual false claim. Id.

In order to properly assert a fraud claim, the complaint must "provide fair notice to defendants and enable them to 'prepare an informed pleading responsive to the specific allegations of fraud.'" U.S. *ex rel.* Bledsoe v. Community Health System, 342 F.3d 634, 643 (6th Cir. 2003) (citing Advocacy Org. for Patients & Providers v. Auto Club, Inc. Assn., 176 F.3d 315, 322 (6th Cir. 1999)). Especially in False Claims Act cases, Rule 9(b) serves "to protect defendants whose reputations may be harmed by meritless claims of fraud, to discourage 'strike suits and to prevent the filing of suits that simply hope to uncover relevant information during discovery.'" Karvelas, 360 F.3d at 232 (citing Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996)). Furthermore, Rule 9(b)'s specificity requirements are not loosened merely because, as in the present case, there are multiple defendants. In U.S. *ex rel.* Bledsoe v. Community Health System, 342 F.3d 634 (6th Cir. 2003), the court stated:

> A complaint may not rely upon blanket references to acts or omissions by all of the defendants, for each of the defendants named in the complaint is entitled to be apprised of the

> circumstances surrounding the fraudulent conduct of which he individually stands charged.

342 F.3d at 643 (citations omitted; emphasis added).

In the present case, the Relators have failed to plead Defendants' alleged fraud with sufficient specificity on multiple levels. For example, the Complaint is extremely vague about exactly what claims were filed with Medicare and other governmental payment programs and by whom. Paragraphs 4, 35 and 92 only state that BRMC submitted claims to Medicare and Medicaid as well as other government programs, but provide no specifics whatsoever. Paragraph 40 states that BRMC "was required to submit cost reports" to Medicare, but the Complaint never alleges that any reports were ever filed, when they were filed, or any specific false content contained in them. Likewise, Paragraph 55 says that "at all times material to this complaint" cost reports were signed by BRMC's CEO "or some other hospital official" who attested to the certification, but does not say when this occurred or if the cost report was actually filed rather than merely signed.

Paragraph 91 of the Complaint alleges, "upon information and belief" V&S and Drs. Vaccaro and Saleh "referred a substantial number of patients to BRMC for in-patient services, radiology services, and other designated health services." However, the Complaint lacks any specifics regarding these purported referrals. There are no specific allegations whatsoever of V&S or Drs. Vaccaro and Saleh referring even one patient who was a beneficiary of Medicare, Medicaid, or any other Government program to BRMC during the time period after the Sublease was executed. Furthermore, the Complaint lacks any specific allegations that V&S

or Drs. Vaccaro and Saleh presented any claims to the Government, let alone any claims that were false.

Paragraph 66 states in a general conclusory fashion that the Defendants "sought reimbursement" from "designated state Medicaid programs" without designating which states or alleging that any false statement or certification was made in connection with the reimbursement that was sought. Similarly, Paragraph 73 contends that the Defendants "submitted Requests for Reimbursement" to TRICARE/CHAMPUS that were based on their submissions to Medicare" but does not say which submissions, presumably because there were no allegations about any specific Medicare submissions either.

These claims fall completely short of the specificity required by Rule 9(b). And the limited situation when Rule 9(b) requirements may be relaxed – when information necessary to plead the relator's claims is in the exclusive control of the defendant – is not applicable here because the alleged false claims, i.e., the Medicare cost report and other claims for payment, are already in the possession of the government and thus not in the exclusive possession of the Defendants. U.S. *ex rel.* Russell v. Epic Healthcare Management Group, 193 F.3d 304, 308 (5th Cir. 1999) (a relaxed Rule 9(b) standard is not appropriate when the requisite information is possessed by entities other than the opposing party). All Medicare cost reports filed by hospitals are readily available on line at http://www.cms.hhs.gov/data/cost_reports/default.asp, so the Relators could have easily accessed any cost reports that had been filed by BRMC.[2]

---

[2] If the Relators had done so, however, they would have been basing their claim on already public information, and thus not qualify as the "original source" of the information contained in the Complaint, since they do not have direct knowledge

2. The Complaint Fails to Adequately Plead an Alleged Conspiracy to Submit False Claims

In addition to alleging that Defendants (i) presented or caused false claims to be presented to the Government, and/or (ii) used false records or statements or caused false records or statements to be used, in relation to getting false claims paid, Relators have also generally alleged that Defendants conspired to defraud the Government. To state a claim for conspiracy under the False Claims Act, Relators are required to allege: an agreement to conspire with one or more persons to get a false or fraudulent claim allowed or paid by the Government, as well as an overt act in furtherance of the conspiracy. U.S. *ex rel.* Atkinson v. Pennsylvania Shipbuilding Co., Civ. No. 94-7316, 2000 WL 1207162 (E.D.Pa. 2000). Furthermore, Relators are required to allege the fraud underlying the purported conspiracy with the particularity required by Rule 9(b). Id.

As set forth in further detail above, Plaintiffs have failed to satisfy Rule 9(b)'s specificity requirements, which require more than general, conclusory allegations of a conspiracy to defraud. See U.S. *ex rel.* Johnson v. Shell Oil Co., 183 F.R.D. 204, 208-09 (E.D. Tex. 1998) (dismissing False Claims Act conspiracy claim for failing to plead with particularity); U.S. *ex rel.* Drake v. Norden Systems, Inc., 2000 WL 1336497 at *12 (D. Conn. 2000) (dismissing False Claims Act conspiracy claim for failing to plead with particularity). Relators' Complaint in this case contains nothing more than conclusory allegations. It lacks any specific allegations of an agreement to get false or fraudulent claims paid, or any specific acts by Defendants in

---

of the alleged violations, thus depriving the Court of jurisdiction under 31 U.S.C. § 3730(e)(4). See U.S. *ex rel.* Paranich v. Sorgnard, 396 F.3d 326 (3d Cir. 2005).

furtherance of such a conspiracy. Accordingly, because the Relators cannot satisfy the particularity requirements of Rule 9(b), the Complaint should be dismissed with prejudice.

3. The Complaint Fails to Specifically Plead That Defendants V&S or Dr. Vaccaro or Saleh Caused a False Hospital Cost Report to Be Filed

As noted above, Relators have failed to specifically allege any false claims submitted by the Defendants to the Government for payment. They seem to be basing their claims in large part upon alleged false certifications contained in Hospital Cost Reports. However, even assuming, *arguendo*, that a false Hospital Cost Report had been specifically and sufficiently pled to support a False Claims Act claim (which it was not), V&S and Drs. Vaccaro and Saleh additionally assert that Relators' Complaint fails to sufficiently allege, with specificity, that they caused any false Hospital Cost Report to be filed.

In order for an individual to be liable under §§ 3129 (a)(1), (a)(2), or (a)(7) of the False Claims Act, he must either (i) present a false claim, record or statement to the Government himself, or (ii) cause a false claim, record or statement to be submitted or used. In the case of third parties who do not actually submit false claims or records to the Government themselves, courts have still found liability under the False Claims Act when the third party spearheaded a scheme or conspiracy which it knew would ultimately lead to a false claim or record being submitted to the Government. See e.g., U.S. *ex rel.* Schmidt v. Zimmer, Inc., 386 F.3d 235 (3d Cir. 2004). In Schmidt, the court held that, for causation purposes, a False Claims Act claim was sufficiently asserted against a seller of orthopedic implants which created a marketing scheme that it knew would, if successful, result in the submission by health care providers of Medicare compliance certificates that the seller knew would be false.

Absent a party being intricately involved in orchestrating a scheme or conspiracy, a False Claims Act cause of action is not viable unless the party (i) instructed another to file a false claim or record, or (ii) took some affirmative action to assist in having a false claim submitted to the Government. See U.S. *ex rel.* Shaver v. Lucas Western Corp., 237 F.3d 932, 933 (8th Cir. 2001); U.S. v. President and Fellows of Harvard College, 323 F.Supp.2d 151, 189 (D.Mass. 2004). In Shaver, the court held that a complaint did not sufficiently assert that an employer, who refused to pay a former employee's medical bills under a workers' compensation order, "caused" the former employee to submit the medical bills to the Government. Shaver, *supra* at 933. Even if the employer knew the employee would submit the bills to the Government, he did not instruct the former employee to submit the bills, and did not "cause" them to be submitted for purposes to the False Claims Act. Id.

In Harvard, the Government asserted False Claims Act claims against a university and two employees for false statements submitted to the Government in relation to certain grants. Based, in part, upon information provided by Jonathan Hay, one of the employees who was involved with a university related grant project, the university submitted documents to the Government containing false statements. Hay knew that the information he provided would ultimately be provided to the Government and potentially result in false claims. The other employee – Andrei Schleifer – did not approve any expenses submitted by the university and took no action to have claims submitted to the Government. The court held that even if Schleifer knew that false claims were going to be submitted and did nothing to stop it, there was

insufficient evidence to establish that he "presented or caused to be presented" false claims. Harvard, *supra* at 188-9.

In the present case, Relators' Complaint specifically alleges that the Hospital Cost Reports were submitted and certified by BRMC. Complaint ¶ 40. The Complaint fails to specifically plead how V&S or Dr. Vaccaro or Saleh made or caused to be made false claims or false statements in any Hospital Cost Reports. It does not allege that V&S or Dr. Vaccaro or Saleh had any input or involvement in the preparation of the Hospital Cost Reports, or even that they reviewed them or had knowledge of their contents, let alone their existence. As in the Shaver and Harvard cases, there is no indication that either V&S or Dr. Vaccaro or Saleh instructed BRMC to file any Hospital Cost Reports or took any affirmative action to assist in the presentation of Hospital Cost Reports.

Moreover, unlike in Schmidt, there are no specific allegations that V&S or Dr. Vaccaro or Saleh created or knowingly pursued a scheme that, if successful, would ultimately result in the submission of a false claim or record to the government. There are no allegations that V&S or Dr. Vaccaro or Saleh did anything other than enter into a lease with BRMC. Nothing about the lease was dependent on any claims being made to the Government or the inclusion of any information in Hospital Cost Reports. There are no allegations that V&S or Dr. Vaccaro or Saleh were required to refer any patients pursuant to BRMC under any agreements with BRMC. In fact, there are no specific allegations that either V&S or Dr. Vaccaro or Saleh actually referred any patients to BRMC, after the lease was executed, whose treatment was reimbursed by any Government program. Accordingly, there are no specific allegations that V&S or Dr. Vaccaro

or Saleh filed or caused to be filed any false Hospital Cost Reports. The Complaint should, therefore, be dismissed with prejudice.

C. The Complaint Is Based on Allegations of Certifications Contained in a Cost Report That Could Not Have Been Filed Prior to the Filing of the Complaint

In addition to failing to satisfy Rule 9(b), the Complaint should be dismissed for another critical reason – it is based on an alleged false claim that could not have happened before the Complaint was filed. The Complaint was filed under seal on July 2, 2004. It alleges that the lease between BRMC and V&S violated the anti-kickback statute and the Stark Law. However, the commencement date of the lease was October 1, 2003. Complaint, Exhibit A, Section 2(a). Obviously, even if all Relators' allegations are taken as true, the lease could not have had an effect on BRMC's Medicare claims until after the lease went into effect.

Paragraph 39 of the Complaint states: "After the end of each hospital's fiscal year the hospital files it Hospital Cost report...." Medicare regulations set the due date for the cost report as the last day of the fifth month following the end of the provider's fiscal year. 42 C.F.R. § 413.24(f)(2). The Pennsylvania Medical Assistance (Medicaid) Program requires all Pennsylvania hospitals to be on a July to June fiscal year. 53 Pa. Code. § 1163.64(c)(2).

Therefore, the October 2003 lease attached to the Complaint could only have affected BRMC's cost report for the fiscal year ending June 30, 2004, a mere two days before the Complaint was filed. But even if no extensions were granted, that cost report would not have been due until November 30, 2004, almost five months after the Complaint was filed. In fact, it *could* not have been filed until after the Complaint was filed. All Medicare claims are held for

billing review for 30 days to determine if they are eligible for payment. Medicare Intermediary Manual, Part 3, Section 3600.1 http://www.cms.hhs.gov/manuals/13_int/a3600.asp#_1_2 . Thus, BRMC could not have begun to complete its cost report until the end of July. Also, the cost report cannot be filed until the "Provider Statistical Reimbursement Report" ("PS&R") is received from the Medicare intermediary, which is not even mailed until 120 *after* the end of the fiscal year, or 30 days before the due date. Medicare Provider Reimbursement Manual Part II, Section 104.A.3 http://www.cms.hhs.gov/manuals/pub152/PUB_15_2.asp (attached as Exhibit 1)[3]; c.f. 68 Fed. Reg. 50719 (Aug. 22, 2003). Thus, the Complaint is based on an event that could not have occurred at the time it was filed. This hardly meets the "claim in hand" standard. A *qui tam* relator cannot base his claim on an event that has not happened yet. See U.S. *ex rel.* Quinn v. Omnicare, Inc., 382 F.3d 432, 439 (3d Cir. 2004); Schmidt, 2005 W.L. 1806502, *supra*.

D. The Complaint Fails to Allege any Violations of the Stark Law

The "Stark Law," codified at 42 U.S.C. § 1395nn, prohibits physicians from making referrals for certain "designated health services" ("DHS") payable by Medicare to an entity (such as a hospital) with which he or she (or an immediate family member) has a financial relationship unless an exception applies. The law also prohibits the entity from filing claims for payment with Medicare for those referred services, unless a statutory or regulatory exception applies.

---

[3] Courts may take judicial notice of matters of public record on government agency web sites when considering a motion to dismiss. In re: Wellbutrin SR/Zyban Antitrust Litigation, 281 F.Supp.2d 751 (E.D. Pa. 2003).

The term "financial relationship" is defined in the Stark Law as including "ownership or investment interests" and "compensation arrangements." 42 U.S.C. § 1395nn(a)(2). The term "compensation arrangement" is defined as meaning any arrangement involving remuneration between the physician or family member and the entity. 42 U.S.C. § 1395nn(h)(1)(A). Thus, a lease between a hospital and a physician could constitute a "compensation arrangement" for Stark purposes.

The Stark regulations, at 42 C.F.R. § 411.354(a)(1), define the term "financial relationship" as:

> (i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or
>
> (ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

The regulations further distinguish between a "direct" and "indirect" relationship as follows:

> (2) A direct financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities.
>
> (3) An indirect financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

Indirect compensation arrangements are defined in § 411.354(c)(2):

> An indirect compensation arrangement exists if—
>
> (i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons

> or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);
>
> (ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under § 411.354(d)(2) or (d)(3). If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and
>
> (iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

The relationship between BRMC and V&S – which is at the heart of the Complaint – is clearly not a direct relationship because it is between a hospital and a professional corporation, and not between a hospital and an individual physician or physicians. Nor is the lease an "indirect"

financial relationship, since such relationships require the aggregate compensation ultimately received by the physician to vary with, or otherwise reflect, the volume or value of referrals or other business generated by that physician for the hospital. The lease (Complaint Exhibit A) establishes on its face that the rental payments from BRMC to V&S do not vary based on the amount of business that either Dr. Saleh or Dr. Vaccaro generates for BRMC. Section 2(d) calls for flat monthly rental payments. Therefore, the lease does not give rise to either a direct or an indirect financial relationship, and the Stark Law does not apply to it at all. As such, Relators cannot assert a Stark Law violation to support a False Claims Act claim. This fact provides further support for why Relators have failed to state a claim upon which relief can be granted and why their Complaint should be dismissed with prejudice.

E. The Complaint Should Be Dismissed With Prejudice Without Leave to Amend

When a court determines that amendment of a complaint would be futile, it is proper for the court to dismiss the complaint without leave to amend. See e.g., Yuhasz v. Brush Wellman, Inc., 341 F.3d 559 (6th Cir. 2003); Old Republic Insurance Company v. Hansa World Cargo Service, Inc., 170 F.R.D. 361 (S.D.N.Y. 1997); In re NAHC, Inc. Securities Litigation, 306 F.3d 1314 (3d Cir. 2002). In Yuhasz, the court held that the relator in a False Claims Act case failed to allege a claim with sufficient specificity as required under Rule 9(b). The relator expressly indicated that he had pled all the facts he knew and could do no more absent discovery. Therefore, the Court of Appeals held that any amendment would be futile, and affirmed the District Court's dismissal of the complaint. Yuhasz, 341 F.3d at 566, 569. Similarly, in Old Republic, the plaintiff in a RICO action conceded that he had no additional facts in which to

plead fraud under his RICO claims. The District Court held that any amendment would be futile, and dismissed the RICO claims with prejudice. Old Republic, 170 F.R.D. at 383-4. In NAHC, the court affirmed the dismissal of shareholders' securities fraud claims without leave to amend. The court held that any amendment to the complaint would be futile, given that (i) several claims were time-barred and (ii) the shareholders failed to identify any additional facts that would have cured other deficiencies in the pleading. NAHC, 306 F.3d at 1332-3.

In the present case, Relators base their False Claims Act claims on extremely vague allegations of false claims and certifications contained in Hospital Cost Reports submitted by BRMC. Relators' alleged false claims purportedly arise out of the lease between BRMC and V&S in September of 2003. At the time Relators filed their Complaint on July 2, 2004, it would have been impossible for BRMC to have filed a Hospital Cost Report covering the lease, since BRMC's fiscal year ended only two days earlier, on June 30, 2004. See Section 2 above.

Accordingly, when Relators filed their Complaint, they made general conclusory references to alleged false claims made in a cost report, which could not even have existed at the time. As in the Yuhasz, Old Republic, and NAHC cases, any leave to amend granted to Relators would be futile. There is no amount of re-pleading that Relators can do to correct this fatal defect. As noted above, even if the Relators now subsequently attempt to base their claims on already public information, they will not qualify as the "original source" of the information contained in the Complaint and the Court will be divested of jurisdiction under 31 U.S.C. § 3730(e)(4). See Paranich, *supra*. It is also too late to cure this problem by subsequent discovery. Numerous courts have refused to allow *qui tam* relators to plead generally and rely

on later discovery to satisfy Rule 9(b) requirements. *See* Karvelas, *supra* at 231 ("allowing a relator to plead generally at the outset and amend the complaint at the 12(b)(6) stage after discovery would be at odds with the FCA's procedures for filing a *qui tam* action and its protections for the government"); Clausen, *supra* at 1313 n. 24 (allowing a plaintiff to "learn the complaint's bare essentials through discovery … may needlessly harm a defendant['s] goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and, at worst, … baseless allegations used to extract settlements"); Russell, *supra* at 309 ("a special relaxing of Rule 9(b) is a *qui tam* plaintiff's ticket to the discovery process that the statute itself does not contemplate"). The Complaint should, therefore, be dismissed with prejudice without leave to amend.

IV. CONCLUSION

For the foregoing reasons, the Complaint should be dismissed as to all Defendants, with prejudice.

Respectfully submitted,

By: /s/
Daniel M. Mulholland III, Esquire
PA I.D. No. 28806
Henry M. Casale, Esquire
PA I.D. No. 42066

HORTY, SPRINGER & MATTERN, P.C.
4614 Fifth Avenue
Pittsburgh, PA 15213
412-687-7677
dmulholland@hortyspringer.com
hcasale@hortyspringer.com

Counsel for Defendant
Bradford Regional Medical Center

Dated: August 25, 2005

By: /s/
Jay D. Marinstein, Esquire
PA I.D. No. 53163
Carl J. Rychcik, Esquire
PA I.D. No. 73754

FOX ROTHSCHILD LLP
625 Liberty Avenue, 29th Floor
Pittsburgh, PA 15222
(412) 391-1334
jmarinstein@foxrothschild.com
crychcik@foxrothschild.com

Counsel for Defendants,
V & S Medical Associates, LLC,
Peter Vaccaro, M.D. and
Kamran Saleh, M.D.

Dated: August 25, 2005

CERTIFICATE OF SERVICE

I hereby certify that a copy of the attached document was filed electronically with the United States District Court for the Western District of Pennsylvania and also served on each of the following attorneys via First Class United States Mail on the date set forth below:

Jay D. Marinstein, Esquire
Carl J. Rychcik, Esquire
Fox Rothschild L.L.P.
625 Liberty Avenue
29th Floor
Pittsburgh, PA 15222-3115

Andrew M. Stone, Esquire
Stone & Stone
828 Frick Building
437 Grant Street
Pittsburgh, PA 15219

Robert L. Eberhart, Esquire
United States Attorney's Office
Civil Division
USPO & Courthouse
Pittsburgh, PA 15219

Michael Granston, Esquire
U.S. Department of Justice
Commercial Litigation Branch
P.O. Box 261
Ben Franklin Station
Washington, DC 20044

August 25, 2005

/s/
Daniel M. Mulholland III